Sterigenics®

Ms. Lerner,

We appreciate your reaching out regarding your story. There are a number of inaccuracies and misleading statements in your email.

Sterigenics Willowbrook operates in compliance with regulations, has a proven record of operating safely and has taken additional voluntary actions to consistently improve operations and outperform what the regulations require. We take very seriously our responsibility to keep safe our communities, our employees, and the patients we serve.

We empathize with those suffering from cancer and other illnesses, and wish the best for them and their families. However, the conclusions you appear to have drawn create a misleading and inaccurate portrayal of Sterigenics and its safe use of EO in the sterilization of vital medical products.

The controversy regarding our Willowbrook facility began with an Agency for Toxic Substances and Disease Registry (ATSDR) study which relied on selectively-chosen, worst-case ambient air samples collected in the vicinity of the Willowbrook facility. In fact, of the 39 total samples collected, ATSDR discarded ALL but the highest level readings. Additionally, the report assumed people in the residential areas would breathe a worst-case level all day, every day for 33 years. By its own admission, the ATSDR "biased [the results] on purpose to try to capture" worst case scenarios that ATSDR assumed would lead to further analysis and discussion.

Furthermore, we now know the ATSDR report relied on flawed test results that the U.S. EPA on November 21, 2018 acknowledged, "may have reported higher ambient levels of ethylene oxide than actually exist."

In terms of the specific assertions you raise, we offer the following responses:

- "...according to the US EPA, the Sterigenics plant in Willowbrook emits ethylene oxide at unsafe levels."
    - The U.S. EPA has not stated that Willowbrook emissions represent unsafe levels.
    - During its webinar on February 5, 2019 to discuss recent air sample results in Willowbrook, the U.S. EPA stated that "it remains premature to draw conclusions about long-term health risks from the data."
    - In a September 27, 2018 letter to Illinois Governor Rauner, the U.S. EPA indicated that Willowbrook is an area identified as "potentially having an elevated chronic risk from ethylene oxide." The letter further clarified, "It is important to note that the air concentrations of ethylene oxide are not high enough to cause immediate harm to health for the people in and around Willowbrook."
    - In addition, the ATSDR on August 29, 2018 clarified an earlier report and said that "[its report from August 22] … was not one that indicated immediate health threat or that there was an emergency situation."

- "…the plant has been emitting dangerous levels of the chemical for 34 years…"

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- The Willowbrook facility operates in compliance with regulations and the permit issued under the federal Clean Air Act by the Illinois EPA. Sterigenics has taken additional voluntary actions to consistently improve operations and outperform what the regulations require.
- The Willowbrook facility's state-of-the-art systems safely control and contain EO. Today, less than 1/10th of 1% of the EO used in the sterilization process is released into the atmosphere, which is a 99.9% control rate – exceeding the regulatory requirement of 99.0% – and representing one of the highest control levels in the country for this industry.

- EO levels compared to IRIS
  - The IRIS risk assessment used by the ATSDR has been widely questioned and criticized by scientists and other experts and remains disputed, even within the U.S. EPA.
  - The "risk" standard is based on levels well below normally occurring EO levels in the Chicago area and other areas of the country – and well below the amount produced by the human body (see detail below). This does not mean that the air is unsafe, but rather that the risk assessment used by ATSDR is illogical.
  - EO is produced by many natural and man-made sources and is in the air all around us.
  - As noted by the U.S. EPA in its February 5, 2019 webinar, the amounts of EO being measured are "extremely low levels in the atmosphere…part per billion and part per trillion numbers and it doesn't take very much of this material or any material to cause those kinds of levels in the air." In addition, "There are other sources of ethylene oxide in the [Willowbrook] area besides the Sterigenics facility."
  - Recent air sample tests across the Chicago area show that the ambient air levels of EO around Willowbrook are consistent with levels found across the Chicago area. On February 5, 2019, the US EPA acknowledged "…it is pretty apparent…that there is background of ethylene oxide in [the Willowbrook] area."

EO Levels vs. IRIS Standard (ug/m^3)					
IRIS Standard	**Ambient Air Willowbrook[1]**	**Ambient Air Burr Ridge[1]**	**Ambient Air Chicago[2]**	**Ambient Air Denver[3]**	**Human Body[4]**
0.0002	0.19	0.23	0.24	0.27	3.4

- EO levels used for ATSDR risk assessment compared to EPA Air Testing Results
  - The US EPA's own air sample tests in Willowbrook – based on which it has indicated "it remains premature to draw conclusions about long-term health risks" – indicate that the levels of EO in the air around Willowbrook are notably lower than the level used in the ATSDR report.
  - The ATSDR based its report on the highest residential and commercial samples among the 39 samples available. In making its risk assessment ATSDR further assumed that

[1] Willowbrook and Burr Ridge air sampling conducted by the villages; Willowbrook samples collected 16-November to 17-November, 2018; Burr Ridge samples collected 13-November to 14-November, 2018.
[2] Samples collected 12-October to 23-October, 2018 and 12-November to 20-November, 2018.
[3] Based on testing conducted by the Colorado Department of Public Health & Environment in December 2018.
[4] Kirman and Hayes, 2017 – derivation of endogenous equivalent values to support risk assessment and risk management decisions for endogenous carcinogen: ethylene oxide.

people would be exposed to those levels 24 hours a day, 365 days a year for 33 years in the case of residential exposure and 25 years in the case of commercial exposure.

- The table below demonstrates that the EO levels vary significantly and the averages from the recent EPA air monitoring are well below the ATSDR levels.

	EPA Air Test Results Range	EPA Results Average	ATSDR Air Level Used	EPA Average vs. ATSDR Levels
Willowbrook Residential Areas	0.11 ug/m^3 to 1.67 ug/m^3	0.39 ug/m^3	2.1 ug/m^3	81% lower
Willowbrook Commercial Areas	0.18 ug/m^3 to 11.7 ug/m^3	2.43 ug/m^3	9.1 ug/m^3	73% lower

EO sterilization is the only FDA-approved method to sterilize millions of critical medical devices. By complying with and going above and beyond what the regulations require, the Sterigenics Willowbrook facility safely uses EO and provides a vital service to patients in Illinois and across the country.

For additional information on the Sterigenics Willowbrook facility please visit www.sterigenicswillowbrook.com